

## **RESPONSE**

### **I. Status of the Claims**

Claims 3 and 4 have been cancelled without prejudice and without disclaimer, as being drawn to non-elected inventions. Claim 1 has been amended and Claim 2 has been cancelled. New claims 5, 6 and 7 have been added. Claims 1, 5, 6 and 7 are therefore presently pending in the case. For the convenience of the Examiner, a clean copy of the pending claims is attached hereto as Exhibit A. In compliance with 37 C.F.R. § 1.121(c)(1)(ii), a marked up copy of the original claims is attached hereto as Exhibit B. A clean copy of the amended title and abstract is attached hereto as Exhibit C and a marked-up copy of the original title and abstract is attached hereto as Exhibit D.

### **II. Support for the Claims**

Claim 1 has been amended to further clarify the claim. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least in Claim 1 and the sequence listing as originally filed.

New Claim 5 has been added to more clearly claim aspects of the invention. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least in claim 2 as originally filed.

New Claim 6 has been added to more clearly claim aspects of the invention. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least at page 10, line 29- page 11, line 2.

New claim 7 has been added to more clearly claim aspects of the invention. Claim 7 finds support throughout the specification as originally filed, with particular support being found at least at page 11, lines 2-8.

As the amendments to Claim 1 and new claims 5, 6 and 7 are fully supported by the specification and claims as originally filed, they do not constitute new matter. Entry therefore is respectfully requested.

### **III. Objections**

The Action objects to the syntax of claims 1 and 2. Applicants submit that revised Claims 1, cancellation of Claim 2 and new Claim 5 have successfully addressed these issues.

The Action objects to the title of the disclosure because it is allegedly not descriptive. Specifically, the Action objects to the use of the term “novel” and because the title contains reference to human transporter proteins and current claims do not claim proteins. Applicants in no way agree and submit that while some might view the use of the term “novel” in the title as redundant it is not non-descriptive, as these are novel sequences. Similarly, while the proteins disclosed in the present application are not claimed in the remaining claims, amino acid sequences encoding proteins of novel human transporters are indeed disclosed and their use described throughout the specification. In addition both of these terms have been acceptable to the U.S.P.T.O. as evidenced at least by the abstracts of issued U.S. Patents Nos: 6,403,784, 6,433,153, 6,441,153 and 6,441,154, 6,444,456 and 6,448,388. However, in order to progress the application more rapidly towards allowance Applicants have amended the title of the present application to read:

Sequences Encoding Human ATP binding Cassette Transporter Proteins.

The Action also objects to the abstract of the disclosure because it allegedly is not concise. Applicants in no way agree and submit that abstracts of this type have been acceptable to the U.S.P.T.O. as evidenced at least by the abstracts of issued U.S. Patents Nos: 6,403,784, 6,433,153, 6,441,153 and 6,441,154, 6,444,456 and 6,448,388. However, in order to progress the application more rapidly towards allowance Applicants have amended the abstract of the present application to read:

Novel human ATP binding cassette transporter polynucleotide and polypeptide sequences are disclosed that can be used in therapeutic, diagnostic, and pharmacogenomic applications.

#### **IV. Rejection of Claims Under 35 U.S.C. § 101**

The Action rejects continues to reject the claims under 35 U.S.C. § 101, allegedly because the claimed invention lacks support by either a specific and substantial asserted utility or a well established utility. Applicants respectfully traverse based on the arguments laid out in the previous response and those outlined below.

Applicants previous response identified incorrect alignment and inaccurate identity for the nucleic acid SEQ ID NO:23. This was the result of a error in which Applicants' representative was forwarded a blast report which he believed was for SEQ ID NO:23 and based his response on the same. However, as Examiner Landsman has rightly pointed out, the sequence in the blast report was not SEQ ID NO:23, rather it was a blast analysis for SEQ ID NO:11 of the present application. Even though Applicants' representative believed he was submitting correct information at the time and in no way intended to mislead Examiner Landsman, Applicants representative apologizes for the error.

It is clear that the novel human transporter described by SEQ ID NO:23 of the present invention encodes a splice variant resulting in a shorter isoform of what has been defined by third party scientists, wholly unaffiliated with Applicants, as encoding ATP-binding cassette, sub-family C, member 11 isoform a; multi-resistance protein 8; ATP-binding cassette transporter MRP8; ATP-binding cassette transporter C11 [*Homo sapiens*] (Accession No. NP\_11572, Exhibit E). Also enclosed, as Exhibit F, is an amino acid sequence comparison of ATP-binding cassette transporter C11 (Accession No. NP\_11572) and SEQ ID NO:24. This amino acid alignment makes it clear that SEQ ID NO:24 represents a shorter isoform, most likely lacking an exon present in the isoform a of ATP-binding cassette transporter C11, Accession No. NP\_11572 .

The present Action (Paper No.14) appears to recognize that the present invention is indeed a splice variant of ATP-binding cassette transporter C11 (ABCC11), based on the choice of references, Tammur *et al.* and Yabuuchi *et al.* used to attempt to discredit Applicants assertion of utility. However these publications support rather than dispute Applicants assertion that the present invention has utility and is a splice variant of ABCC11. For example, Tammur *et al.*, in the final paragraph of the introduction (page 90, 4<sup>th</sup> paragraph), state that they had undertaken a long-term project of cloning new human ABC transporters and linking them to various disease phenotypes and have identified ABCC11 and ABCC12 as two such members. Thus, clearly, Tammur et al., recognize the value and utility of ABCC11 and ABCC12 and their association with paroxysmal kinesigenic

choreoathetosis and infantile convulsions with paroxysmal choreoathetosis, human inherited diseases. In addition, with regard to function, Tammur *et al.*, state on page 93, lines 8-10 that “it would be reasonable to suggest that ABC11 and ABCC12 could share functional similarities with ABCC4 and ABCC5.” Said function being recognized by the art as the transport of organic anions, nucleotide analogs and cyclic nucleotides. Thus rather than contradicting the utility of the present invention the conclusions of Tammur *et al.* support the position that those of skill in the art would recognize Applicants’ asserted utility of the present invention as credible.

Yabuuchi *et al.* clearly supports Applicants’ assertion that the present invention is a splice variant of ABCC11, for there appear to be many such variants. And although these authors speculate that “splice variants may represent diverse biological functions” (emphasis added), this speculation is not supported by any data or based on any fact or reference and thus appears to be pure speculation, “Therefore, it is of interest to know whether some of these splice variants...represent biological functions” (pg 937, lines 17-19). However, Yabuuchi *et al.* also recognize in their concluding remarks the utility of ABCC11 with regard to paroxysmal kinesigenic choreoathetosis, and therefore also support Applicants’ utility assertions as credible.

Therefore, it is clear that the present invention defines a novel human transporter protein, a splice variant of ATP-binding cassette transporter C11 (ABCC11) and that the present invention has utilities that are credible to those of skill in the art and well-established. As such, the described inventions utility is in full compliance with the provisions of 35 U.S.C. section 101. Applicants therefore respectfully request that the rejection be withdrawn.

#### **V. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph**

The Action continues to reject the claims under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the claimed invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully disagree. As demonstrated extensively in section III, above, the present invention is supported by a specific, substantial, credible and well-established utility. The function of the protein encoded by the sequences of the present invention is that of a transporter, more specifically a ABC transporter.

Applicants submit that as the claims have been shown to have a specific, substantial, credible

and well established utility, as detailed in section III, above. Applicants therefore respectfully request that the rejection of claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

The Action rejects claims 1-2 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants in no way agree with the Examiner's position that original Claim 1 lacks enablement. The skilled artisan would easily recognize 24 contiguous nucleic acids derived from any of the nucleic acid sequences described in the sequence listing and would also know how to use a nucleic acid molecule that comprises 24 contiguous bases of nucleic acid sequence of SEQ ID NO:23. In fact, Applicants note that the entire DNA gene chip industry is based on the use of 24 or more contiguous bases of nucleic acid sequence. Therefore, Applicants submit that those of skill in the art would also be able to make and use the present invention. However, Applicants submit that this rejection has been avoided by revision of Claim 1 to read on the full-length molecule, which those of skill in the art would clearly recognize as an ATP-binding cassette transporter and know how to make and use it. Therefore, Applicants respectfully request that the rejection of Claim 1 under 35 U.S.C. § 112, first paragraph, be withdrawn.

#### **VI. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph**

The Action rejects Claim 2 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention.

Specifically, first the Action rejects Claims 1 and 2 as allegedly indefinite based on the term "stringent hybridization conditions". While Applicants submit that the term is sufficiently definite, as a number of stringent hybridization conditions are defined in the specification and would be known to those of skill in the art, solely in order to progress the case more rapidly toward allowance, Applicants have cancelled Claim 2 and added new Claim 5 consistent with the suggestion by the Examiner, to remove condition (b) regarding hybridization, and thus this issue has been rendered moot and avoids rejection. Applicants, therefore, respectfully request withdrawal of this rejection.

The Action also rejects Claim 2 as allegedly indefinite based on the phrase "complement thereof". While Applicants submit that the term is sufficiently definite and would be known to those of skill in the art, solely in order to progress the case more rapidly toward allowance, Applicants have cancelled

Claim 2 and added new Claim 5 consistent with the suggestion of the Examiner, to remove condition (b) regarding hybridization, and thus the phrase "complement thereof" and this issue has been rendered moot and the rejection avoided. Applicants, therefore, respectfully request withdrawal of this rejection.

**VII. Rejection of Claims Under 35 U.S.C. § 102(a)**

The Action rejects claim 1 under 35 U.S.C. § 102(a), as being anticipated by Mahairas *et al.* (Proc. Natl. Acad. Sci. 96:9739-9744, 1999) and by Adams *et al.* (Accession No. B47956). While Applicants do not necessarily agree with the present rejection, as claim 1 has been amended to recite the complete nucleotide sequence of SEQ ID NO:23, which is neither taught nor suggested by Mahairas *et al.* or Adams *et al.*, Applicants submit that the rejection of Claim 1 under 35 U.S.C. § 102(a) has been thus avoided, and respectfully request withdrawal of the rejection.

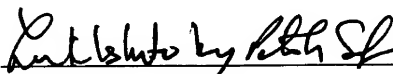
**VIII. Conclusion**

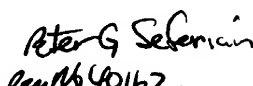
The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Landsman have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

November 11, 2002

Date

  
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